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FEB 4 2008

Premarket Notification 510(k) Summary

1) **Submitter Information**

b) Company Name and Address:

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c) Contact Name:

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d) Date Prepared: February 1, 2008

2) **Name of Device**

b) Trade Name: Medacta Total Hip Prosthesis System (Quadra S® Femoral Stem, CoCrMo Femoral Ball Heads and Tri-Plus™ Cup System)

c) Common Name: Total Hip Prosthesis System

d) Classification Name and Reference: Part 888.3350 Hip joint metal/polymer semi-constrained cemented prosthesis; Product Code JDI

3) **Substantial Equivalence Claimed to Predicate Device**

Total Hip Prosthesis System Component	Predicate Device /Manufacturer	K #
Quadra® S	SL-PLUS® and SLR-PLUS® Stems, Plus Orthopedics AG	K001942
	SL-PLUS® Lateralized Stem, Plus orthopedics AG	K021178
CoCrMo Femoral Ball Head	Portland Cobalt Chrome Femoral Head, Portland Orthopaedics, Ltd.	K063278

Total Hip Prosthesis System Component	Predicate Device /Manufacturer	K #
Tri-Plus™ Cup System	Not applicable, previously cleared acetabular cups and liners	K042565

4) **Device Description**

The components of the Medacta Total Hip Prosthesis System are intended for single, cementless use, only, and are described below:

a) Quadra® S Femoral Stem

The Quadra® S Femoral Stem is intended for cementless use, and is available in four versions, standard or lateral stem, both in regular or short neck version. The Quadra® S Femoral Stem is intended, as a component of the Medacta Total Hip Prosthesis System, for use in total or partial hip arthroplasty and in primary or revision surgery.

The Quadra® S Femoral Stem is manufactured from a titanium alloy, according to ISO 5832-11, 1994, Implants for surgery -- Metallic materials -- Part 11: Wrought titanium 6-aluminium 7-niobium alloy. The stem is sandblasted and the neck has a mirror-polished finish.

The Quadra® S Femoral Stem may be used with the Tri-Plus™ Cup System and CoCrMo Femoral Ball Heads.

b) Cobalt Chromium Molybdenum (CoCrMo) Femoral Ball Head

The CoCrMo femoral ball head is intended for mechanical fixation to a mating hip stem such as the Quadra® S Femoral Stem and for use in total or partial hip arthroplasty to provide increased patient mobility and reduced pain by replacing the damaged hip joint, in primary or revision surgery.

The CoCrMo femoral ball heads are manufactured from Cobalt Chromium Molybdenum, according to ISO 5832-12, 2007, Implants for surgery -- Metallic materials -- Part 12: Wrought cobalt-chromium-molybdenum alloy.

The CoCrMo femoral balls heads range in diameter from 28 mm to 32 mm and may be used with the Quadra® S Femoral Stem and Tri-Plus™ Cup System.

c) Tri-plus™ Cup System

The Tri-plus™ Acetabular shell is a true hemispherical design featuring plasma spray coating which allows the substrate to retain its fatigue strength characteristics. The shell and liner utilize a secure locking mechanism designed to decrease the potential for polyethylene wear debris. The liner is manufactured from direct-compression molded polyethylene and incorporates anti-rotation features. The locking mechanism allows for

secure fixation between the shell and liner. Superior surface tabs designed into liner provides anti-rotation stability and proper liner indexing. The shell is a true hemisphere design available in No-hole, Cluster hole, and Multi-hole options. The liners are available in Neutral and Hooded (10°) options. The Tri-plus™ liners are manufactured from DCM polyethylene. The Tri-plus™ Cup System may be used with the Quadra® S Femoral Stem and CoCrMo femoral ball heads.

5) **Intended Use / Indications for Use**

The Medacta Total Hip Prosthesis System is intended for cementless use in total or partial hip arthroplasty and in primary or revision surgery.

Hip replacement is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid polyarthritis, or congenital hip dysplasia
- Avascular necrosis of the femoral head
- Acute traumatic fracture of the femoral head or neck
- Failure of previous hip surgery, joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement

6) **Predicate Device Comparison of Indications for Use / Intended Use and Technical Characteristics**

The comparison of the Medacta Total Hip Prosthesis System was based on a review of relevant Design Control documentation, which are included in the company's 510(k) Premarket Notification, and information concerning the predicate devices that was obtained from the FDA web site and the predicate device manufacturers' web sites. The comparison considered technological characteristics and the indications for use / intended use.

7) **Performance Data**

Note: No performance standards applicable to this device have been adopted under Section 514 of the Food Drug and Cosmetic Act, with respect to the applicable classifications or product codes.

The materials used to manufacture Medacta Total Hip Prosthesis System components conform to the following FDA recognized standards:

a) Materials:

Quadra® S Femoral Stem: ISO 5832-11, 1994, Implants for surgery -- Metallic materials -- Part 11: Wrought titanium 6-aluminium 7-niobium alloy

CoCrMo Femoral Ball Head: ISO 5832-12, 2007, Implants for surgery -- Metallic

materials -- Part 12: Wrought cobalt-chromium-molybdenum alloy

b) Sterility:

ISO 11137-1:2006, Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

ISO 11137-2, 2006, Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose

c) Performance Testing:

Design verification and design validation, e.g., bench testing was performed according to FDA's Design Control Requirements, Title 21 Code of Federal Regulations, Part 820.30, and in accordance to FDA recognized standards for mechanical testing.

8) **Conclusion**:

The information and data provided in this 510(k) Premarket Notification establish that the Medacta Total Hip Prosthesis System is substantially equivalent to the afore-mentioned predicate devices with respect to indications for use/intended use, and technical characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 4 2008

MEDACTA International SA
% Quintiles Consulting
Ms. Pamela J. Weagraff
Principle Consultant
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Norfolk, MA 02056

Re: K072857
Trade/Device Name: Medacta Total Hip Prosthesis
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip joint metal/polymer/metal semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JDI
Dated: January 7, 2008
Received: January 8, 2008

Dear Ms. Weagraff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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ODE Indications Statement

510(k) Number (if known): *Unknown*

Device Name: Medacta Total Hip Prosthesis System

Indications for Use:

The Medacta Total Hip Prosthesis System is intended for cementless use in total or partial hip arthroplasty and in primary or revision surgery.

Hip replacement is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid polyarthritis, or congenital hip dysplasia
- Avascular necrosis of the femoral head
- Acute traumatic fracture of the femoral head or neck
- Failure of previous hip surgery, joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement

Prescription Use: X	AND/OR	Over-the-Counter Use:
(21 CFR 801 Subpart D)		(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bruchman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072457